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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/682,460

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Kenneth E. Kadziauskas

27564

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7590

11/12/2008

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EXAMINER

HAND, MELANIE JO

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

11/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/682,460	Applicant(s) KADZIAUSKAS ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) 6,8,12,13,19,21,34,36 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-11,14-18,20,22,23,29-33,35,37-39,41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia (U.S. Patent No. 6,106,494).

With respect to **claim 1**: Saravia discloses an infusion source for an ocular surgery in the form of fluid management system 20 comprising a fluid supply in the form of supply bags (not shown), an irrigation line in the form of inflow tube 28 interconnecting said fluid supply bags and an irrigation lumen in the form of first low-loss cannula 30, and a tubular member in the form of accumulator 29 separate from, and in a parallel fluid relationship with, said irrigation line and in fluid communication with said irrigation line 28 and said irrigation lumen 30. The tubular member

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29 has an expandable wall configured to expand during occlusion of the irrigation lumen 30 during pressure buildup at the surgical site.

Saravia discloses that the tubular member 29 is separate from the irrigation line 28, but discloses that it is in serial fluid relationship with the line, rather than in a parallel fluid relationship with said irrigation line 28. However Saravia discloses that the accumulator 29 remedies drastic increases in pressure in a surgical site (e.g. the joint capsule of the knee), and the accumulator prevents backflow of fluid from the site. Since this backflow can also cause contamination of the draining line, and such an accumulator would be equally capable of preventing backflow of suction, it would be obvious to one of ordinary skill in the art to modify the system of Saravia such that an additional accumulator placed in the draining outflow line 34 is separate from, and in parallel fluid communication with, the irrigation line 28, to prevent backflow or drainage pressure buildup. The expandable wall of the accumulator in the outflow aspiration line 34 suggested by Saravia is configured to expand during occlusion of an aspiration lumen 32 due to pressure buildup at a surgical site disclosed by Saravia.

With respect to **claim 3**: The tubular member 29 is disposed in serial fluid communication with said irrigation line 28 and irrigation lumen 30.

With respect to **claim 4**: The tubular member wall 198 is formed from an elastic material, namely an elastic balloon.

With respect to **claim 15**: The tubular member 29 is disposed proximate the handpiece 38.

With respect to **claim 16**: The tubular member 29 is disposed in serial fluid communication with said irrigation line 28 and irrigation lumen 30.

With respect to **claim 17**: The tubular member wall is formed from an elastic material, namely an elastic balloon 198.

4. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia ('494) in view of Urich (U.S. Patent No. 7,083,591).

With respect to **claim 2**: The tubular member 29 disclosed by Saravia is disposed proximate a handpiece, defined collectively by hand controller 38 by either the grippable portion of cannula 30 or the grippable portion of cannula 32. The handpiece disclosed by Saravia is not effective for use in a phacoemulsification procedure. Urich discloses a tubular member proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. ('448, Col. 1, lines 10-14, Col. 4, lines 43-45) The devices of Saravia and Urich seek to solve a similar problem in the art, i.e. providing a hand controllable and manipulable means for delivering fluid and suction to a surgical site. Thus, it would be obvious to one of ordinary skill in the art to modify the infusion source disclosed by Saravia by replacing the hand controller and cannulas with the handpiece disclosed by Urich with a reasonable expectation of success to allow use of the system in ocular surgery.

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With respect to **claim 14**: The infusion source disclosed by Saravia comprises a handpiece, however the handpiece that comprises a cannula with said irrigation lumen 30. However the cannula is not a needle. Ulrich teaches an infusion source comprising: a surgical instrument 11 considered herein to be a handpiece inasmuch as Ulrich teaches that the instrument 11 has a tip 12 for insertion into the cornea for use in a known emulsification procedure that cannot be accomplished with a non-handheld device. The handpiece 11 has a needle in the form of sleeve 14 with sharp tip 12 positioned therein at an end of said sleeve 14 with an irrigation lumen defined by the inner wall of sleeve 14 (Col. 2, lines 14-23) The devices of Saravia and Ulrich seek to solve a similar problem in the art, i.e. providing a hand controllable and manipulable means for delivering fluid and suction to a surgical site via an irrigation lumen in the form of a cannula. Thus, it would be obvious to one of ordinary skill in the art to modify the infusion source disclosed by Saravia by replacing the hand controller and cannula with the handpiece disclosed by Ulrich having a needle with a reasonable expectation of success to allow use of the system in ocular surgery.

5. Claims 5, 7, 9, 18, 20, 22 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia ('494) in view of Rehn et al (JP 2000-120602 A) (English translation).

With respect to **claim 5**: Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. ('602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member

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disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With respect to **claim 7**: Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. The sheath 12 disclosed by Rehn is flexible. ('602, ¶0021) The motivation to modify the infusion source of Saravia such that the tubular member comprises a sheath disposed around said expandable wall is stated *supra* with respect to claim 5.

With respect to **claim 9**: Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to

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applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

With respect to **claim 18**: Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. ('602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With respect to **claim 20**: Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. The sheath 12 disclosed by Rehn is flexible. ('602, ¶0021) The motivation to modify the infusion source of Saravia such that the tubular member comprises a sheath disposed around said expandable wall is stated *supra* with respect to claim 18.

With respect to **claim 22**: Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is

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examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also *MPEP* § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

With respect to **claim 41**: Saravia discloses an accumulator 29 for a surgical handpiece, collectively 38,30,32 comprising a tubular portion comprising an expandable elastic wall in the form of an elastic balloon. The accumulator 29 is configured to expand upon accumulation of fluid within the tubular member, and is therefore necessarily configured to expand during occlusion of an aspiration lumen.

Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. (‘602, ¶0021) Therefore, it would be

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obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With regard to the limitation “an ocular surgical handpiece”, since the device of Saravia meets all of the limitations of claim 43 as to a surgical handpiece containing an irrigation lumen, the surgical handpiece disclosed by Saravia is fully capable of use in ocular surgery. With regard to the limitation “to enhance the flow of fluid into an ocular surgical handpiece upon clearing of the occlusion”, since the accumulator is configured to provide such accumulation of fluid in an irrigation lumen or aspiration lumen, the accumulator 29 is also configured to enhance the flow of fluid into the surgical handpiece 38,30,32 upon clearing of the occlusion.

With respect to **claim 42**: Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

With respect to **claim 43**: Saravia discloses an infusion source for a surgical handpiece 38,30,32 comprising an irrigation fluid supply in the form of supply bags (not shown), an irrigation line in the form of inflow tube 28 connected to the irrigation fluid supply for supplying fluid to a surgical handpiece. The source also comprises an accumulator 29 in fluid communication with the irrigation line 28. The accumulator 29 comprises an expandable elastic wall configured to expand, and is thus also configured to expand upon accumulation of fluid. As such, the accumulator 29 disclosed by Saravia is necessarily configured to provide accumulation of fluid within the tubular member during occlusion of an aspiration lumen, inasmuch as it is configured to provide accumulation of irrigation fluid within an irrigation lumen. Since the accumulator is configured to provide such accumulation of fluid in an irrigation lumen or aspiration lumen, the accumulator 29 is also configured to enhance the flow of fluid into the surgical handpiece 38,30,32 upon clearing of the occlusion.

Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. (‘602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so

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as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With regard to the limitation “an ocular surgical handpiece”, since the device of Saravia meets all of the limitations of claim 43 as to a surgical handpiece containing an irrigation lumen, the surgical handpiece disclosed by Saravia is fully capable of use in ocular surgery.

With respect to **claim 44**: Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

6. Claims 29-32 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia ('494) in view of Sepielli (U.S. Patent No. 5,554,894).

With respect to **claim 29**: Saravia discloses a surgical system for performing surgery comprising a handpiece connected to cannulas 30 and 32 for delivering and draining fluid through cannulas 30 and 32, respectively, driven by a controller in the form of hand controller 38. The system also comprises an irrigation lumen defined by cannula 30, a fluid supply in the form of supply bags (not shown), an irrigation line in the form of inflow tube 28 interconnecting said fluid supply and said irrigation lumen 30. the system comprises a tubular member in the form of accumulator 29 separate from said irrigation line 28 and in fluid communication with said irrigation line 28 and said irrigation lumen 30. The tubular member 29 has an expandable wall defined by balloon 198 configured to expand-during occlusion of the irrigation lumen 30 due to pressure buildup from a surgical site.

Saravia discloses that the tubular member 29 is separate from the irrigation line 28, but discloses that it is in serial fluid relationship with the line, rather than in a parallel fluid relationship with said irrigation line 28. However Saravia discloses that the accumulator 29 remedies drastic increases in pressure in a surgical site (e.g. the joint capsule of the knee), and the accumulator prevents backflow of fluid from the site. Since this backflow can also cause contamination of the draining line, and such an accumulator would be equally capable of preventing backflow of suction, it would be obvious to one of ordinary skill in the art to modify the system of Saravia such that an additional accumulator placed in the draining outflow line 34 is separate from, and in parallel fluid communication with, the irrigation line 28, to prevent backflow or drainage pressure buildup. The expandable wall of the accumulator in the outflow

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aspiration line 34 suggested by Saravia is configured to expand during occlusion of an aspiration lumen 32 due to pressure buildup at a surgical site disclosed by Saravia.

Saravia does not disclose that the handpiece is driven by a controller through a power line. Sepielli teaches a footswitch 101 for controlling a surgical phacoemulsification handpiece for ophthalmic surgery that is connected to said handpiece via a power line in the form of cable 115 having connector 123. (Col. 4, lines 15-19) Sepielli teaches that the footswitch supplies power to the handpiece remotely and allows the surgeon to adjust the power settings or preset patterns remotely via switches 105, 107, 109, 111 and a touch-screen display 133, therefore it would be obvious to one of ordinary skill in the art to modify the device of Saravia such that said handpiece driven by a controller is driven through a power line as taught by Sepielli to provide a means for remotely powering and controlling the handpiece to prevent unnecessary interruption of surgery for adjustment. ('894, Col. 3, lines 28-38)

With regard to the limitation "an ocular surgical system for performing ocular surgery on an eye" since the system of Saravia as modified by Sepielli meets all of the limitations of claim 29, the system of Saravia as modified by Sepielli renders this limitation obvious.

With respect to **claim 30**: The tubular member 29 disclosed by Saravia is disposed proximate the handpiece 38, 30, 32.

With respect to **claim 31**: The tubular member 29 disclosed by Saravia is disposed in serial fluid communication with said irrigation line 28 and irrigation lumen 30.

With respect to **claim 32**: The tubular member wall disclosed by Saravia is formed from an elastic material, namely an elastic balloon 198.

With respect to **claim 45**: Saravia discloses an infusion source 20 for a surgery comprising a fluid supply in the form of supply bags (not shown), The source also comprises an irrigation line in the form of inflow tube 28 interconnecting said fluid supply and the irrigation lumen 30, and an elongate tubular member in the form of accumulator 29 disposed in fluid communication with said irrigation line 28. The tubular member 29 has an expandable wall that is necessarily configured to expand and thus is configured to expand during occlusion of an aspiration lumen inasmuch as it is configured to expand upon occlusion of the irrigation lumen 30.

Saravia discloses a handpiece in the collective form of hand controller 38 and cannulas 30 and 32, including an irrigation lumen defined by cannula 30. However Saravia does not disclose that the hand controller itself includes the irrigation lumen. Sepielli teaches a footswitch 101 for controlling a surgical phacoemulsification handpiece for ophthalmic surgery that is connected to said handpiece via a power line in the form of cable 115 having connector 123. (Col. 4, lines 15-19) Sepielli teaches that the footswitch supplies power to the handpiece remotely and allows the surgeon to adjust the power settings or preset patterns remotely via switches 105,107,109,111 and a touch-screen display 133. Since the devices of Saravia and Sepielli seek to solve a similar problem in the art (i.e. provide fluid via a handpiece to a surgical site) and the device of Sepielli combines the handheld components with the lumens and controls for an easily manipulable handpiece, it would be obvious to one of ordinary skill in the art to modify the device of Saravia such that said handpiece is replaced with the handpiece disclosed by Sepielli to provide an easily manipulable means for remotely powering and controlling the handpiece to prevent unnecessary interruption of surgery for adjustment. ('894, Col. 3, lines 28-38)

7. Claims 33, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia ('494) in view of Sepielli (U.S. Patent No. 5,554,894) as applied to claim 29 above, and further in view of Rehn et al (JP 2000-120602 A) (English translation).

With respect to **claim 33**: Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. ('602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With respect to **claim 35**: Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. The sheath 12 disclosed by Rehn is flexible. ('602, ¶0021) The motivation to modify the infusion source of Saravia such that the tubular member comprises a sheath disposed around said expandable wall is stated *supra* with respect to claim 33.

With respect to **claim 37**: Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is

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examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

Allowable Subject Matter

8. Claims 10, 11, 23, 24, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

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9. The following is a statement of reasons for the indication of allowable subject matter: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests an infusion source comprising a tubular member having a plurality of expandable walls molded in a spaced apart relation within a sheath. The closest prior art of record is the combined teaching of Saravia and Rehn. The combined teaching meets all of the remaining limitations of the claimed invention. However, it is examiner's position that neither Saravia, nor Rehn, alone or in combination with one another, discloses or suggests a plurality of expandable walls molded in a spaced apart relation. This is based upon Saravia's disclosure of only one expandable wall and no sheath, and no suggestion to mold additional walls in a spaced apart relation either inside or outside of the expandable balloon. Thus Saravia teaches away from the limitation of claims 10, 11, 23, 24, 38 and 39. Rehn discloses a cover part 12 and sleeve 20, either of which can function as a sheath as claimed. If the sleeve 20 is the sheath, then there are plural walls that are unified in a spaced apart relationship in a manner that fairly suggests a plurality of expandable walls molded in spaced apart relation. However the only suggestion Rehn discloses for the sleeve 20 as a flexible sheath is that the placement of flexible sleeve 20 is known to those in the art of brake pipes. Thus, there is no motivation for one of ordinary skill in the art of fluid accumulators for surgical handpieces disclosed by Rehn to modify the device of Saravia or Rehn so as to provide a plurality of expandable walls in spaced apart relation within a sleeve or sheath. As such, neither Saravia nor Rehn, alone or in combination with one another, discloses or fairly suggests the limitation of claims 10, 23 and 38. Claims 11, 24 and 39 depend, respectively, from claims 10, 23 and 38 and are thus also indicated here as being directed to allowable subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761